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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-30977
Telephone: (513) 679-2700
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June 8, 1999

WARNING LETTER
CIN-WL-99-209

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

William S. Gandee D.C., President
Natural Revelations Inc.
2050 S. Arlington Road
Akron, Ohio 44306

Dear Dr. Gandee:

This letter is in reference to your firm's marketing and distribution of the product "Nature's Gel". The label for this product states that it contains menthol, eucalyptus oil, and capsicum as the active ingredients.

Labeling claims in the brochure titled "NATURE'S GEL" include:

- Nature's Gel can be used effectively for the relief of pain from a number of different causes, such as Arthritis, Bursitis, Tendinitis, Rheumatism, Carpal Tunnel Syndrome. Contusions, Cramps, Tension Headaches and Shin Splints.
- PREVENTION: Nature's Gel is very effective in preventing injuries if used prior to any activity. Many people use pain-relieving gels after they hurt, but with Nature Gel's active ingredients, cayenne and eucalyptus and its ability to dilate the capillaries for better circulation, it can decrease sore muscles and injuries. "An ounce of prevention is worth a pound of cure".
- Cayenne is great for the circulatory system and is considered one of the greatest of all herbs. When used with other herbs, it acts as a catalyst and increases the effectiveness of the other herbs. It is especially good when used as liniment for Headaches, Rheumatism and Muscle Aches.
- Eucalyptus helps to dilate capillaries for better circulation and is very effective when used in conjunction with other herbs. Eucalyptus contains antiseptic and healing properties when used in conjunction with other herbs. Eucalyptus contains antiseptic and healing properties; it's great for soothing stiffness and swelling and provides relief against the pain of arthritis and rheumatism.

The Nature's Gel label states that it is for "*Arthritis *Bursitis *Simple Backache *Muscle Aches *Rheumatism *Sprains *Strains *Sport Injuries *For Prevention Use Prior To Exercise."

Based on its intended uses cited Above, Nature's Gel is an external analgesic drug (section 201(g) of the Federal Food, Drug and Cosmetic Act [the Act]). Even though there is no final monograph (FM) for this class of OTC drug products, the agency on November 7, 1990 published a Final Rule establishing that certain ingredients in OTC drug products are not generally recognized as safe and effective and are misbranded. This Final Rule states that after May 7, 1991, any OTC drug product with eucalyptus oil which is intended for use as an external analgesic is subject to regulatory action if marketed in the United States (21 CFR 310.545(10(ii)) as a new drug (section 210(p) of the Act) and may not be legally marketed in the United States since it is not approved (section 505 of the Act). Additionally, this drug remains an unapproved new drug if reformulated without Eucalyptus based on its claims.

This drug is misbranded (section 502(f)(1)), because it's labeling fails to bear adequate directions for use.

The Nature's Gel label does not indicate that Natural Revelations, Inc. is only the distributor and not the manufacturer. This causes the product to be misbranded under Section 502(b) of the Act.

This letter is not intended to be an all-inclusive review of all labeling and products that your firm markets. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations. (This includes all labeling and promotional materials).

We request that you take prompt action to correct these violations. Failure to promptly correct violation may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug and Cosmetic Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations. You should also include an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, please state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to Lawrence E. Boyd, Compliance Officer, Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237-3097.

Sincerely,

Henry L. Fielden
District Director
Cincinnati District